



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/518,810

04/20/2006

Peter Gibson

22409-00323-US

7516

30678

7590

04/24/2009

CONNOLLY BOVE LODGE & HUTZ LLP

1875 EYE STREET, N.W.

SUITE 1100

WASHINGTON, DC 20006

EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/518,810 | Applicant(s) GIBSON ET AL. | |
| | Examiner REX HOLMES | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-11 and 19-23 in the reply filed on 4/6/09 is acknowledged.
2. Claims 12-18 and 24-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/6/09.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2-3 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 2 is vague as it is unclear if the implantable tissue stimulating device is a cochlear electrode array, further includes a cochlear electrode array, or if the elongate carrier member is the cochlear electrode array.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 3762

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4-5 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Borkan (U.S. Pub. 2002/0156513).

8. Borkan discloses an elongated tissue stimulating device that includes a carrier (e.g. 50) with a plurality of electrodes (e.g. 54), with multiple lumens that extend at least halfway (e.g. 70, 72), with optic fibers in the lumens or drug channels (e.g. 70, ¶ 60). Borkan discloses that one channel is for light the other is for camera optics and the tip of the device is rounded (e.g. ¶ 59).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3762

11. Claims 1-11 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milojevic et al. (U.S. Pub. 2004/0147825 hereinafter "Milojevic") in view of Salerno (U.S. Pat. 5,394,865).

12. Milojevic discloses an implantable stimulating device that includes an elongated carrier having a plurality of electrodes (e.g. ¶ 70) and a first lumen (e.g. ¶ 134) and a body made of flexible, resilient, translucent silicone rubber (e.g. ¶¶ 63-66). Milojevic further discloses that the lumen can be used to deliver substances or be used to hold a stylet for implantation of the device (e.g. ¶ 134). Milojevic discloses that the device is straightened when the stylet is inserted and curved when the stylet is withdrawn from the device (e.g. Figs. 21-23). Milojevic further discloses an implantable stimulator/receiver connected to the carrier member for sensing and stimulating (e.g. ¶¶ 11, 14, 136, 145, 147, 202, 221). Milojevic discloses the claimed invention except for the stylet having one or more optic fibres. However, Salerno discloses a fiber view lighted stylet that includes multiple fibre optic cables capable of transmitting light and visual information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stylet as taught by Milojevic, with lighted stylus as taught by Salerno, since such a modification would provide the predictable results of a stylus with optic fibers for providing the predictable results of lighting the implantation area and allowing the physician to view the implantation area for proper placement of the device.

13. Regarding claim 8, Milojevic in view of Salerno discloses the claimed invention except for the carrier member having two lumens. It would have been obvious to one

Art Unit: 3762

having ordinary skill in the art at the time of invention was made to have included two lumens, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

14. Claims 2-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan (U.S. Pub. 2002/0156513) as applied to claims 1, 4-5 and 9-11 above, and further in view of Milojevic et al. (U.S. Pub. 2004/0147825 hereinafter "Milojevic").

15. Borkan discloses a bendable tissue stimulating device (e.g. Figs. 12, 14) including optical channels for light and cameras as described above but fails to expressly disclose that it is positioned within a cochlea. However, Milojevic discloses a similarly sized and shaped device that includes an elongated carrier having a plurality of electrodes (e.g. ¶ 70) and a first lumen (e.g. ¶ 134) and a body made of flexible, resilient, translucent silicone rubber (e.g. ¶¶ 63-66). Milojevic further discloses that the lumen can be used to deliver substances or be used to hold a stylet for implantation of the device (e.g. ¶ 134). Milojevic discloses that the device is straightened when the stylet is inserted and curved when the stylet is withdrawn from the device (e.g. Figs. 21-23). Milojevic further discloses an implantable stimulator/receiver connected to the carrier member for sensing and stimulating the cochlea (e.g. ¶¶ 11, 14, 136, 145, 147, 202, 221, Fig. 16, Abstract). Borkan discloses the claimed invention except for the device specifically being used for cochlear implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the elongated stimulation device as taught by Borkan, with stimulation of the cochlea as

Art Unit: 3762

taught by Milojevic, since such a modification would provide the predictable results of stimulating the cochlea with a similarly sized and shaped electrode for providing a means of positioning the device using optical channels to optimize positioning and ultimately stimulation of the cochlea.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762